

IP 06-1558-C b/s Eli Lilly v. Mayne Pharma
Judge Sarah Evans Barker

Signed on 8/28/07

INTENDED FOR PUBLICATION AND PRINT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

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| ELI LILLY AND COMPANY, |) | |
| |) | |
| Plaintiff, |) | |
| vs. |) | NO. 1:06-cv-01558-SEB-JMS |
| |) | |
| MAYNE PHARMA (USA) INC., |) | |
| |) | |
| Defendant. |) | |

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| Plaintiff, |) | |
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| |) | |
| MAYNE PHARMA (USA) INC., |) | |
| Defendant. |) | |

ORDER DENYING DEFENDANT’S MOTION TO DISMISS

This cause is before the Court on the Motion to Dismiss [Docket No. 12] filed by Defendant, Mayne Pharma (USA) Inc. (“Mayne Pharma”). Defendant contends that this court lacks personal jurisdiction over it and seeks dismissal. Plaintiff Eli Lilly and Company (“Lilly”) maintains that this court does have personal jurisdiction over Defendant, and further, that if this court determines there is no personal jurisdiction, the proper remedy is not to dismiss, but rather to transfer the case to the District of Delaware. For the reasons detailed in this entry, we DENY Defendant’s Motion.

Lilly brought this action against Mayne Pharma on October 24, 2006. Lilly’s complaint alleges that Mayne Pharma infringed on two Lilly patents¹ by filing an Abbreviated New Drug Application (“ANDA”) with the FDA seeking approval to manufacture, use, and sell an injectable form of the chemotherapy drug gemcitabine hydrochloride, a generic form of the drug Lilly markets as GEMZAR®.

On December 20, 2006, Defendant filed this Motion to Dismiss asserting lack of personal

¹ The patents at issue are U.S. Patent Nos. 4,808,614 and 5,464,826. Compl. ¶¶ 6-7.

jurisdiction. On Lilly's motion, Magistrate Judge Shields opened a period of jurisdictional discovery regarding Defendant's contacts with Indiana, and granted Lilly an enlargement of time to respond to Defendant's motion until after the completion of such discovery. See Docket No. 32.

Factual Background

Mayne Pharma, a developer and marketer of generic and specialty injectable drug products, is a Delaware corporation with its principal place of business in Paramus, New Jersey. Mayne Pharma's products are primarily used in hospitals for therapeutic purposes in such areas as oncology, anesthesia/pain and cardiac care. Hannon Aff. ¶ 3.

Mayne Pharma has no telephone connection, telephone listing or bank account in Indiana. Hannon Aff. ¶ 5. It maintains it does not own, lease, or rent offices, real estate, buildings, warehouses, plants, facilities, assets or other real property in Indiana. Id. Mayne Pharma does not pay taxes in Indiana nor has it commenced any legal proceedings in Indiana. Id. Its manufacturing facilities are located outside Indiana in Boulder, Colorado and Aguadilla, Puerto Rico.² Id. ¶ 3. Mayne Pharma does not have a Certificate of Authority to do business in Indiana, nor it is required to file a biennial report with the Secretary of State of Indiana. Id. ¶ 4. It claims that it does not have any employees, officers or agents working from or residing in Indiana. Id.

² Mayne Pharma does, however, have a contract with Enzon Pharmaceuticals, Inc. ("Enzon"), to have its Multi-Vitamin Infusion ("MVI") product packaged into individual vials at Enzon's plant in Indianapolis. Hannon Dep. at 81. Mayne Pharma determines when the bulk material will be shipped to Enzon and how much will be packaged. Id. at 83. Then, pursuant to Mayne Pharma's instructions, Enzon ships the packaged product to Mayne Pharma's warehouse in Texas. Id. at 82-84.

However, Mayne Pharma acknowledges that it has three Regional Sales Managers who supervise Mayne Pharma's accounts throughout the United States and 29 Territory Sales Managers who are each assigned a territory that covers a number of states or parts of states. Hannon Aff. ¶¶ 6-7. While none of these sales managers is based or resides in Indiana, at least two³ of the Territory Managers cover a territory that contains parts of Indiana and make periodic sales visits to hospitals in Indiana. Id. ¶ 7.

Mayne Pharma does not have an Indiana State Wholesale Pharmaceutical Distribution license, nor does it have its own distribution network in Indiana. Hannon Aff. ¶ 8. Most of its sales are made via independent wholesalers that distribute and sell the products of many different pharmaceutical manufacturers. Id. These wholesalers purchase products from Mayne Pharma and then resell them to entities, including Indiana entities, who are members of "group purchase organizations" ("GPOs"). Hannon Dep. at 36. Mayne Pharma does not direct these wholesalers or control where or to whom they sell, but it does determine the price that the GPO gets from the wholesaler. Id. at 36-37. Mayne Pharma negotiates prices for particular products with a GPO and then when a member of the GPO wants to buy a Mayne Pharma product from a distributor, it will pay that price. Id.

Each month, the wholesalers generate "charge-back" reports that are given to Mayne Pharma and distributed to the sales representatives. These reports list the customers who purchased products, where those customers are located, and the types and quantity of products

³ Lilly reports that in 2004-2005, Mayne employed a Specialty Hospital Sales Representative, who promoted only the MVI product. Pl.'s Resp. at 4. This special representative was assigned parts of Indiana during this time period in addition to the two Territory Managers who already covered areas in the state. Id. Thus, at times, there were three Mayne Pharma representatives who conducted business in Indiana.

that were purchased. Hannon Dep. at 77-78. Mayne Pharma then uses those reports to analyze which customers are buying which products in order to help determine potential business opportunities for the future. Id. at 78.

In addition to these indirect sales through wholesalers, Mayne Pharma's sales representatives also engage in direct contact with Indiana purchasers. Mayne Pharma's Regional Managers create "target lists" that they periodically give to their Territory Managers to identify potential business. Hannon Dep. at 69. The Territory Managers responsible for areas in Indiana, for example, get a target list of Indiana entities that they can then choose to solicit or visit for business. Id. at 68-69. These lists are created in part based upon the information Mayne Pharma receives in the charge-back reports from its wholesalers. Id. at 78-79. Mayne Pharma does not require its sales representatives to contact the entities on the target lists, nor are the sales representatives required to visit every area in their territory. Luburich Dep. at 66-67. For example, Territory Managers do not have to visit a state in the territory at all if they choose to focus their efforts elsewhere in the territory and are still able to meet their sales goals. Cheslick Dep. at 80. However, the sales force is incented by Mayne Pharma by additional pay in excess of their routine compensation if they do sell to an entity on the list or if one of the wholesalers makes a target list sale. Hannon Dep. at 69. The Indiana target list for July 2006 that was given to the Territory Managers included over 100 names of Indiana entities. See Ex. 12.

Total sales⁴ realized by Mayne Pharma through a combination of these business channels amounted to more than \$2.1 million for the twelve-month period ending in November 2006 (\$1.8

⁴ The total sales numbers are calculated by adding the dollar amount of the indirect sales to the dollar amount of the direct sales for each year. Hannon Dep. at 33.

million in indirect sales plus \$392,000 in direct sales) to over 200 purchasers of Mayne Pharma products in Indiana. Pl.'s Resp. at 1-2. In the calendar years of 2003 through 2006, Lilly reports that Mayne Pharma's total sales in Indiana were approximately \$951,000 in 2003, \$2.1 million in 2004, \$1.4 million in 2005, and \$1.5 million in 2006. *Id.* at 2-3.

Mayne Pharma's Indiana Marketing Efforts

Mayne Pharma's marketing efforts in Indiana involve in-person sales visits, telephone calls, e-mail exchanges and communications by fax. Mayne Pharma has characterized these contacts as "occasion[al]" and "unscheduled." Ex. 8 (resp. to interrog. no. 2). However, in deposition testimony, Monica Monteho Luburich, whose territory as a Mayne Pharma sales representative included Northwest Indiana, stated that her meetings were typically scheduled in advance over the telephone or through e-mail. Luburich Dep. at 63-64.

The exact number of sales visits and other contacts by telephone, e-mail, or fax that Mayne Pharma's sales representatives have made in Indiana cannot be calculated because the only records of such activity are Mayne Pharma's expense reports, which do not include a breakdown of individual accounts within each city visited. Luburich Dep. at 86-87. However, through calculations based on the recollection of the Territory Managers whose territory included Indiana, Lilly reports that Mayne Pharma representatives make approximately 162 customer visits to Indiana per year.⁵ Pl.'s Resp. at 5.

⁵ This number was derived from calculations based on the testimony of two of Mayne Pharma's Territory Managers who were responsible for parts of Indiana. One Territory Manager, Monica Montejo Luburich, reported that she traveled to Indiana one to two times each quarter (approximately every six to seven weeks) for two or three days and estimated that she visited 15 customers during each visit. Luburich Dep. at 59-60. Another Territory Manager, (continued...)

At these sales meetings, the Territory Managers have the authority to discuss pricing with the customers and enter into rebate agreements allowing customers to purchase Mayne Pharma's products at lower prices, or to receive rebates after purchasing, in order to encourage customers to purchase Mayne Pharma's products from the wholesalers or from Mayne Pharma directly. Hannon Dep. at 117-18. During sales calls Territory Managers often leave promotional materials with the customers, including Mayne Pharma's product catalog and other product-specific items like inserts or literature on new products. Cheslick Dep. at 40. The Territory Managers also send faxes to customers informing them about Mayne Pharma's new products. Id. at 47-48.

In addition to the sales visits, the Territory Managers communicate with their Indiana customers via telephone and e-mail. For example, Lilly reports that a telephone record of one of Mayne Pharma's Territory Managers from November 2006 revealed at least twenty-two phone calls to customers in Indiana over the span of four days.⁶ Pl.'s Resp. at 6. Mayne Pharma has also produced a series of e-mails between one of its Territory Managers and the pharmacy purchasing director of Clarian Health in Indianapolis discussing individual contracts and the available pricing options for two Mayne Pharma products. Ex. 16.

Legal Analysis

⁵(...continued)

Kristin Cheslick, testified that she made sales visits to Indiana two days each month and visited between two to five customers each day during those visits. Cheslick Dep. at 31-32. Lilly arrived at its number by averaging these figures (after taking one manager's maternity leave into account) and adding them together. See Pl.'s Resp. at 4-5.

⁶ Lilly notes that Mayne Pharma provided no other similar records. Pl.'s Resp. at 6.

I. Standard of Review

Federal Rule of Civil Procedure 12(b)(2) requires dismissal of a claim where personal jurisdiction is lacking. When “[a] defendant moves to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction, the plaintiff bears the burden of demonstrating the existence of jurisdiction.” Purdue Research Foundation v. Sanofi-Synthelabo, S.A., 338 F.3d 773, 782 (7th Cir. 2003). When a district court rules on a defendant’s motion to dismiss based on the submission of written materials, the plaintiff “need only make out a prima facie case of personal jurisdiction” and “is entitled to the resolution in its favor of all disputes concerning relevant facts presented in the record.” Id. (internal citations omitted).

Federal Circuit law governs personal jurisdiction issues in patent infringement cases. See Hildebrand v. Steck Mfg. Co., 279 F.3d 1351, 1354 (Fed. Cir. 2002). A district court may properly exercise personal jurisdiction over a non-resident defendant if a two-step analysis is undertaken and satisfied. First, the party resisting the exercise of jurisdiction must be amenable to service of process under the state’s long-arm statute; second, the exercise of personal jurisdiction must comport with the due process clause of the Constitution. Id. Because Indiana’s long-arm statute, Indiana Rule of Trial Procedure 4.4(a), “expand[s] personal jurisdiction to the full extent permitted by the Due Process Clause” (LinkAmerica Corp. v. Albert, 857 N.E.2d 961, 966 (Ind. 2006)), the sole question before us is whether due process would be offended were we to exercise personal jurisdiction over Mayne Pharma.

For a court to acquire personal jurisdiction over a defendant, due process requires “that the defendant have such ‘minimum contacts’ with the forum state as will make the assertion of jurisdiction over him consistent with ‘traditional notions of fair play and substantial justice[.]’”

Lakeside Bridge & Steel Co. v. Mountain State Const. Co., 597 F.2d 596, 600 (7th Cir. 1979), quoting International Shoe v. Washington, 326 U.S. 310, 316 (1945). In other words, a defendant must have “fair warning that a particular activity may subject them to the jurisdiction of a foreign sovereign.” Burger King Corp. v. Rudzewicz, 471 U.S. 462, 472 (1985), quoting Shaffer v. Heitner, 433 U.S. 186, 218 (1977) (Stevens, J., concurring in judgment).

Personal jurisdiction may be either specific or general. A court exercises specific jurisdiction over a defendant where the cause of action arises out of or relates to a defendant’s purposefully established contacts with the forum state. Helicopteros Nacionales de Columbia, S.A. v. Hall, 466 U.S. 408, 414 (1984); Burger King Corp., 471 U.S. at 472. General jurisdiction, however, “is proper when a defendant has ‘continuous and systematic business contacts’ with a state and it allows a defendant to be sued in that state regardless of the subject matter of the lawsuit.” Premiere Credit of North America, LLC v. AAT Fabrication, Inc., 2005 WL 1123636, at *2 (S.D. Ind. 2005), citing Helicopteros, 466 U.S. at 416; see also Hyatt Int’l Corp. v. Coco, 302 F.3d 707, 713 (7th Cir.2002); RAR, Inc. v. Turner Diesel, Ltd., 107 F.3d 1272, 1277 (7th Cir.1997). Lilly is not alleging that specific jurisdiction exists over Mayne Pharma in this case (Pl.’s Resp. at 16); therefore, we shall address only whether an exercise of general jurisdiction is proper.⁷

The constitutional requirement for general jurisdiction is “considerably more stringent” than that required for specific jurisdiction. United States v. Swiss American Bank, Ltd., 274 F.3d 610, 619 (1st Cir. 2001); ESAB Group, Inc. v. Centricut, Inc., 126 F.3d 617, 623 (4th

⁷ We note, for the record, that neither the preparation nor the filing of the ANDA took place within Indiana. Def.’s Mem. at 11.

Cir.1997) (“[T]he threshold level of minimum contacts to confer general jurisdiction is significantly higher than for specific jurisdiction.”). “[The] contacts [required for general jurisdiction] must be so extensive to be tantamount to [defendant] being constructively present in the state to such a degree that it would be fundamentally fair to require it to answer in an Indiana court in any litigation arising out of any transaction or occurrence taking place anywhere in the world.” Purdue Research Foundation v. Sanofi-Synthelabo, S.A., 338 F.3d 773, 787 (7th Cir. 2003).

II. Discussion

Mayne Pharma characterizes its contacts with Indiana as quite minimal, stating that “[t]he few interactions [it] has had with Indiana have been limited and sporadic, and are not related to Plaintiff’s claim in this action.” Def.’s Mem. at 1. It points to several cases holding that limited sales within a forum state, even when combined with additional sporadic contacts with that forum, are insufficient to satisfy the requirements of due process. See, e.g., Merck & Co. v. Barr Laboratories, Inc., 179 F. Supp. 2d 368 (D. Del. 2002) (refusing to exercise personal jurisdiction when the total revenue the defendant derived from the forum state was less than one percent of its total revenue, even though its account manager made additional contacts with the forum state by visiting existing customers there approximately three times per year). Further, it contends that consideration of indirect sales (which are first routed through an out-of-state wholesaler) improperly invokes a “stream of commerce” theory, which is inapposite in the

general jurisdiction analysis.⁸ See, e.g., Magla Prods., L.L.C. v. Chambers, 2006 WL 3545442, at *3 (D.N.J. 2006). Finally, Mayne Pharma argues that, even if indirect sales are taken into account to determine its total sales, those sales are nonetheless insufficient to justify the exercise of personal jurisdiction because they comprise, at most, only one and a half percent⁹ of Mayne Pharma's total sales throughout the United States. Cf., e.g., L.H. Carbide Corp. v. Piece Maker Co., 852 F. Supp. 1425 (N.D. Ind. 1994) (declining to exercise personal jurisdiction where the defendant made eight percent of its total sales in the forum state).

Lilly rejoins that the Federal Circuit has held that millions of dollars in sales, without further contacts, *may* be a basis for general personal jurisdiction. Lilly cites the analysis in 3M Innovative Props. Co. v. InFocus Corp., 2005 WL 361494 (D. Minn. 2005), in support of this proposition. In that case, the defendant produced a part used to construct projection televisions and the televisions with the allegedly infringing part were eventually sold through retailers such as Best Buy and Circuit City in the forum state. Id. at *1. In support of its decision to exercise personal jurisdiction in that case, the court noted that “the Federal Circuit has indicated that where the defendant makes regular sales in the forum that result in millions of dollars of revenue, those sales are entitled to significant weight in general jurisdiction analysis” and that those sales alone could be sufficient for exercising personal jurisdiction. Id. at *3 (citing Delta Sys., Inc. v.

⁸ In its Complaint, Lilly initially alleged that we should exercise personal jurisdiction over the defendant in part because it had introduced goods into the “stream of commerce” with the intent that they would be distributed in Indiana. As Defendant properly notes, this “stream of commerce” theory cannot serve as a basis for an exercise of *general* jurisdiction. See Purdue, 338 F.3d at 788. Lilly has since abandoned this line of reasoning. Pl.’s Resp. at 16.

⁹ There is some disagreement between the parties as to the exact percentage of Mayne Pharma's total Indiana sales as a percentage of its U.S. sales. However, our analysis is not affected by this disagreement.

Indak Mfg. Corp., 2001 WL 103518 (Fed. Cir. 2001)). Though the allegedly infringing product is not being sold in Indiana, Lilly maintains that Mayne Pharma's revenues from its other products – approximately \$5.6 million in sales over four years – derived through sales to at least 200 customers in Indiana establish continuous and systematic contacts with the forum.

In addition, Lilly argues, Mayne Pharma's regular and consistent contacts with Indiana customers – approximately 162 in-person sales calls each year and significant additional contact over the telephone, through faxes, and by e-mail – serve as a sufficient basis for personal jurisdiction. Lilly also highlights Mayne Pharma's use of the charge-back reports and target lists to identify and solicit potential business prospects to show that Defendant gives its sales representatives an incentive to generate greater sales in Indiana by putting Indiana entities on the target list. Pl.'s Resp. at 7-8.

It is clear to us that Mayne Pharma does have continuous and systematic contacts with Indiana which permit an exercise of general personal jurisdiction over it here. The fact that Mayne Pharma sells products in Indiana through out-of-state, independent wholesalers, rather than through "direct" sales to Indiana customers, does not change our conclusion. The presence of a wholesaler "middleman" does not insulate Mayne Pharma from its having purposefully availed itself of the forum state by generating millions of dollars worth of commercial activity in Indiana through its sales efforts. Mayne Pharma clearly intended such effects by actively encouraging them through targeted marketing efforts within Indiana. Fanimation Design & Mfg., Inc. v. Nicor, Inc., 2003 WL 21766572, at *6 (S.D. Ind. 2003) ("The scope of what constitutes doing business is not . . . narrow. A company need not be selling directly to consumers to be doing business in the state. [Because the defendant] regularly contacted

distributors of its products in the state . . . to promote its products[, t]he Court is hard pressed to call this purposeful availment either random or fortuitous.”). The frequent and numerous sales visits and other marketing efforts Mayne Pharma conducted within Indiana to encourage such sales also constitute continuous and systematic contacts which support an exercise of jurisdiction. Compare Best Lock Corp. v. Ilco Corp., 32 U.S.P.Q.2d 1223 (S.D. Ind. 1994) (exercising general jurisdiction when defendant shipped over half a million dollars’ worth of products to 37 customers in Indiana each year, stating that “[w]ith that much activity it cannot be said that [the defendant] would not fairly expect to be haled into court in Indiana”); 3M Innovative Properties Co., 2005 WL 361494 (exercising general jurisdiction when defendant generated \$3.8 million in revenue from sales – only 0.64% of its total sales – in the forum state, and defendant’s employees had made 21 visits to the forum state in one year).

Both Lilly and Mayne Pharma have focused much of their argument and analysis on the amount of direct and indirect sales in Indiana, the percentage of Mayne Pharma’s total Indiana sales as a percentage of its U.S. sales, and whether those numbers reach an appropriate threshold in order for this court to exercise general jurisdiction. While the total sales numbers are important factors in the analysis, “[i]t is the overall nature of the activity, rather than its quantitative character” that must be analyzed to determine whether the court has personal jurisdiction. Simplicity, Inc. v. MTS Products, Inc., 2006 WL 924993, at *5 (E.D. Pa. 2006) (quoting Romann v. Geissenberger Mfg. Corp., 865 F. Supp. 255, 261 (E.D. Pa. 1994)). Regular business solicitation in the forum state, especially the solicitation of new customers, is an important aspect of the nature of the activity. E.g., Merck & Co., 179 F. Supp. 2d at 373 (declining to exercise personal jurisdiction, in part because the defendant visited the forum state

no more than three times per year and those visits were not to solicit new business but merely to see existing customers). Here, Mayne Pharma's Territory Managers not only pay calls on existing customers during their visits to Indiana, they also actively solicit new customers in the State using the target lists created by Mayne Pharma's Regional Managers as guides. Additionally, its Territory Managers often enter into rebate agreements with customers to encourage them to purchase Mayne Pharma's products, negotiate pricing options for products with GPOs, and fax information to Indiana customers regarding new products that are available.

In our view, an exercise of jurisdiction over Mayne Pharma is completely reasonable, in taking a balanced view of the various policy considerations, including the burden on the defendant, the interests of the forum state, plaintiff's interest in obtaining relief, the efficient resolution of controversies, and the interest of the states in furthering social policies. Viam Corp. v. Iowa Export-Import Trading Co., 84 F.3d 424, 429 (Fed. Cir. 1996). Mayne Pharma's arguments do not convince us that based on these factors an exercise of jurisdiction would be for them unreasonable or unfair. In light of Mayne Pharma's significant contacts with the forum, and in the absence of convincing evidence to the contrary, we conclude that litigating here would not be unreasonably burdensome. Moreover, the quantity of Mayne Pharma's pharmaceutical sales directed to Indiana gives this state a substantial interest in the resolution of the suit. Therefore, we conclude that the motion to dismiss must be denied and the court shall proceed to exercise personal jurisdiction over Mayne Pharma.¹⁰

¹⁰ Because we have concluded that an exercise of personal jurisdiction over Mayne Pharma is warranted, we do not address Lilly's argument that, if we were to find that jurisdiction (continued...)

Having determined that personal jurisdiction over Mayne Pharma can properly be exercised in this district, we DENY Defendant's Motion to Dismiss. IT IS SO ORDERED.

Date: _____

Copies To:

Robert D. Bajefsky

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

robert.bajefsky@finnegan.com

Jan M. Carroll

BARNES & THORNBURG LLP

jan.carroll@btlaw.com

James F. Hurst

WINSTON & STRAWN LLP

jhurst@winston.com

Charles Edmund Lipsey

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

charles.lipsey@finnegan.com

Robert Francis McCauley

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

robert.mccauley@finnegan.com

Robert Frederic Shaffer

¹⁰(...continued)
were lacking over Mayne Pharma, the proper remedy would be to transfer to the District of Delaware, rather than dismiss the case.

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP
robert.shaffer@finnegan.com

Howard I. Shin
WINSTON & STRAWN LLP
hshin@winston.com

Gail J. Standish
WINSTON STRAWN LLP
gstandish@winston.com

Sally F. Zweig
KATZ & KORIN
szweig@katzkorin.com